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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,763	11/17/2000	Victor E. Shashoua	CMX-001. US	7035
29425	7590	01/15/2004	EXAMINER	
LEON R. YANKWICH YANKWICH & ASSOCIATES 201 BROADWAY CAMBRIDGE, MA 02139			DESAI, ANAND U	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/715,763

Applicant(s)

SHASHOUA, VICTOR E.

Examiner

Anand U Desai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-56, 62-89, 92, 93, 95-99 and 104-117 is/are pending in the application.
- 4a) Of the above claim(s) 1-56, 62-87 and 110-117 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 88, 92, 93, 95-99, and 104-109 is/are rejected.
- 7) ☒ Claim(s) 89 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.                      6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Invention 185, directed to claims 88-103, drawn to a method of preparing a dietary supplement or pharmaceutical composition, in Paper filed on November 12, 2003 is acknowledged. The traversal is on the ground(s) that application of a patentably distinct criterion is improper. This is not found persuasive because the application was filed under 35 U.S.C. 111(a) and is not a national stage application filed under 35 U.S.C. 371, thus the pluralities of inventions are considered distinct as explained in the test of the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 57-61, 90, 91, 94, 100-103 are cancelled. Claims 1-56, 62-87, and 110-117 have been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions. Claims 88, 89, 92, 93, 95-99, and 104-109 are currently under examination.

### ***Priority***

2. Applicant's claim for domestic priority to U.S. Provisional Application Serial Number 60/166,381, filed November 18, 1999, under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 88, 89, 92, 93, 95-99 of this application. The provisional application does not disclose the chemical composition capable of upregulating glutathione peroxidase. Therefore, the priority date is the filing date, November 17, 2000.

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### *Specification*

3. The disclosure is objected to because of the following informalities:

The specification contains underlined words, such as Free Radicals in Biology and Medicine on page 1 and Solid-Phase Peptide Synthesis on page 21, “\_” is normally intended to indicate added matter. See 37 CFR 1.121(b). Suggest removing underlines.

- (b) *Specification other than the claims and listings provided for elsewhere (§ 1.96 and 1.825) —*
- (1) *Amendment by instruction to delete, replace, or add a paragraph.*  
Amendments to the specification, other than the claims and listings provided for elsewhere (§§ 1.96 and 1.825), may be made by submitting:
- (i) An instruction, which unambiguously identifies the location, to delete one or more paragraphs of the specification, replace a deleted paragraph with one or more replacement paragraphs, or add one or more paragraphs;
  - (ii) Any replacement or added paragraph(s) in clean form, that is, without markings to indicate the changes that have been made; and
  - (iii) Another version of any replacement paragraph(s), on one or more pages separate from the amendment, marked up to show all the changes relative to the previous version of the paragraph(s). The changes may be shown by brackets (for deleted matter) or underlining (for added matter), or by any equivalent marking system. A marked up version does not have to be supplied for an added paragraph or a deleted paragraph as it is sufficient to state that a particular paragraph has been added, or deleted.

The use of the trademark “TWEEN 80” has been noted on page 36, line 12, “PHARMACIA” on page 50, line 21, “QEVA” on page 59, line 8, and “BIO-RAD LABORATORIES” on page 59, line 21 in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

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There is a typographical error on page 45, line 25. It appears "Delbecco's" is intended to be "Dulbecco's".

Appropriate correction is required.

***Claim Objections***

4. Claim 89 is objected to because the peptide compound to be selected from contains multiple distinct inventions as described in the requirement for restriction. The peptide compound elected after the restriction requirement consists of:

Asp Gly,

Asp Gly Asp,

Asp Gly Asp Gly Asp (SEQ ID NO:4),

Asp Gly Asp Gly Phe Ala (SEQ ID NO:5),

Asp Gly Asp Gly Asp Phe Ala (SEQ ID NO:6).

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 99 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 99 describes a combination of a gene, what is a "combination of a gene"?

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 88, 92, 93, 95-99, 104-106, 108, and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shashoua, V. U.S. Patent 6,627,601 (Effective filing date=February 10, 1998) in view of Jornot et al. (Biochem. J. 1997 326:117-123) and in further view of Thomas et al. U.S. Patent 5,972,985 (Effective filing date=November 3, 1997). Shashoua, V. teach the method of increasing neuronal activator protein-1 (AP-1) transcription factor comprising administering an isolated polypeptide (U.S. Patent '601, claim 1). The polypeptide can be a modified version of Asp Gly Asp Gly Asp Phe Ala Ile Asp Ala Pro Glu (U.S. Patent '601, SEQ ID NO:1). The modification can be the deletion of one or more of the terminal calcium coordination residues. The modification results in a polypeptide which has a reduced length as compared to the original peptide (U.S. Patent '601, see column 6, lines 36-47, current application, claims 88, 92, 93, 104, and 105). Shashoua, V. also teach the conjugation of the isolated polypeptide to compounds which facilitate transport across the blood-brain barrier (BBB), such as docosahexaenoic acid group (DHA), polylysine, and polyarginine (U.S. Patent '601, see column 12, line 47 through column 12, line 9, current application, claims 88, 92, 93, 95-98). Shashoua, V. also teach a pharmaceutical composition which comprises an isolated polypeptide and a pharmaceutically acceptable carrier (U.S. Patent '601, see column 3, lines 61-65, current application, claims 88, and 106). Shashoua, V. does not teach the

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administration of an isolated polypeptide that is capable of upregulating an antioxidative enzyme. Jornot et al. teach the upregulation of glutathione peroxidase, an antioxidative enzyme, due to the presence of tumor promoting agent responsive elements (TREs). TRE is the binding site for the transcription factor activator protein-1 (AP-1) (see page 117, Introduction 2<sup>nd</sup> paragraph and page 122, Discussion 3<sup>rd</sup> paragraph, current application, claims 88, 99, and 109). Thomas et al. teach nutraceutical compositions that contain a plant source useful as a dietary supplement which have antioxidant properties (U.S. Patent '985, column 1, lines 50-63, current application, claims 106, and 108). One would have been motivated to prepare a dietary supplement or pharmaceutical composition comprising a modified polypeptide as taught by Shashoua, V., which increases AP-1 expression and thereby upregulates an antioxidative enzyme, glutathione peroxidase, with a pharmaceutical acceptable excipient to reduce the toxic affects associated with oxidative free radicals. Therefore, it would have been obvious to the person having ordinary skill in the art to prepare a pharmaceutical composition consisting of a peptide compound and a suitable vehicle by mixing the peptide compound with a suitable vehicle (current application, claims 88, 92, 93, 95-99, 104-106, 108, and 109).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai whose telephone number is (703) 305-4443. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 4:30 p.m..

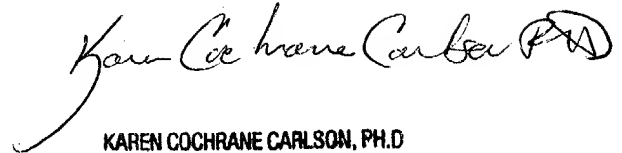
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

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January 6, 2004

A handwritten signature in black ink, appearing to be 'A. D. S.', written in a cursive style.A handwritten signature in black ink, reading 'Karen Cochrane Carlson' followed by a circled 'Ph.D.'.

KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER